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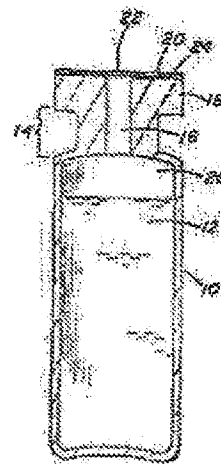
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(54) STERILIZABLE HERMETICALLY-SEALED GLASS CONTAINER AND ITS PRODUCTION METHOD

(57)Abstract:

PROBLEM TO BE SOLVED: To provide a sterilizable hermetically sealed container for a calibrant or reference fluid for blood gas analysis where the liquid has at least one dissolved gas.

SOLUTION: The vial is a glass container with at least one opening 16. The dimension of the opening ranges from that which is just effective for the addition and removal of fluids to that which is the smallest side of the container. A flange 18 circumferentially extends around the opening 16. The vial has the liquid that does not fill the vial to leave room for a head space 26. The head space 26 is present in an amount of the volume percent of the vial ranging from 1 to 99 compared to the amount of the liquid. The vial 10 is sealed with an air impermeable seal 20 comprised of an adhesive polymer contacting the vial and a metal surface facing externally from the vial. Before the vial is sealed by heat or induction sealing a cap or chemical coupling agents are used to hold the seal on the vial. The vial can optionally be sterilized depending on the applications.



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CLAIMS

[Claim(s)]

[Claim 1]It is a container in which sterilization seal for accommodating a fluid which has at least one sort of solution gas is possible, a) It is a glassware means to have at least one opening at the end, For receipts and payments of a fluid, a size of this opening is a range from an effective size of population to a size of the minimum side of this container, surround this opening, and an edge is extended, and thickness of this edge, In order to secure this opening from wall thickness of this container, substantially to a glassware means and b air which are the ranges to thickness slightly smaller than a radius of a container by impermeableness. This opening so that may be a seal which has at least two surfaces, the first surface may be metal, the second surface may be adhesive polymer and an outflow of gas may be suppressed substantially to a wrap sake. A seal with which this second surface of this seal touches sufficient surface area of this container, And are a fluid containing c fluid and gas, and this fluid dissolves and contains gas of at least one sort of known amounts, A hermetic container which is dedicated so that it may leave headspace in this container in quantity which does not fill this container thoroughly, and has the percent by volume to this headspace of this fluid in less than about 99 to about 1% of range, containing a fluid and which can be sterilized.

[Claim 2]Said glassware means has an opening of a diameter of a range up to about 1 to about 10 millimeters at the end, This glassware means has an inside diameter up to at least 3 to about 50 millimeters, Said seal of impermeableness substantially is impermeableness also at oxygen and carbon dioxide, And said fluid with oxygen tension in a range to 0 to 760 mm Hg, and a carbon dioxide partial pressure in a range to 0 to 760 mm Hg. The container according to claim 1 which is a standard fluid [finishing / a pressure survey] which has the concentration of atmospheric gas beyond one sort or it, such as oxygen and/or carbon dioxide.

[Claim 3]The container according to claim 1 which has cylindrical shape.

[Claim 4]The container according to claim 1 whose percents by volume of said headspace to said fluid are about 77 to about 23 percents by volume.

[Claim 5]The container according to claim 1 by which said headspace is filled with an inert gas atmosphere.

[Claim 6]The container according to claim 1 by which said headspace is filled with a gas atmosphere chosen from oxygen, carbon dioxide, those mixtures and one sort or a mixture with inactive gas beyond it, and a group, ** and others.

[Claim 7]The container according to claim 6 whose concentration of said carbon dioxide concentration of said oxygen is within the limits from below external concentration to more than external concentration, and is a range from below external concentration to more than external concentration.

[Claim 8]The container according to claim 6 with which said opening of said glassware means has a comparatively small diameter also in the range of an opening size when oxygen exists in said fluid.

[Claim 9]The container according to claim 1 which said fluid is equilibrated by mixed gas containing carbon dioxide, oxygen, and inactive gas, and is filled with the gas as what was used for preparing this balanced fluid with said same headspace.

[Claim 10]Said fluid Sodium chloride, potassium chloride, ammonium chloride, a lithium bromide, An alkaline metal and alkaline earth metal chlorides, such as potassium phosphate and sodium phosphate, A bromide and a phosphorylation thing, Water-soluble hydrogencarbonates, such as an alkaline metal and/or an alkaline-earth-metals hydrogencarbonate, And aerated water matter lithium, sodium bicarbonate, potassium bicarbonate, A hydrogencarbonate containing aerated water matter magnesium, ammonium acid carbonate, and aerated water matter dimethylammonium, A hydrogencarbonate to which a cation originates in

ammonia or amine; It reaches, . Buffer solution, in order not to be influenced by addition of absorption or acid of carbon dioxide, or a base but to maintain pH. The container according to claim 1 with which it is solution which contains other buffer salts and fused salt chosen from a group, ** and others, one sort or more, and a salt of a quantity effective in order to obtain a suitable pressure so that said fluid may be equilibrated by at least one sort of gas exists.

[Claim 11]The container according to claim 1 filled with a gas atmosphere chosen from a group which said headspace becomes from nitrogen, carbon bisulfide, carbon monoxide, methane, other hydrocarbon gas, ozone, and its unreacted mixture.

[Claim 12]The container according to claim 1 in which said seal is a layer of adhesive polymer which are the amount ethylene of Polymer Division, and a copolymer of vinyl acetate.

[Claim 13]The container according to claim 1 by which coupling agent processing is carried out in order that a glass surface of said edge may promote adhesion for said glassware means of said seal.

[Claim 14]It is the container according to claim 1 including a cap which fixes said seal to said glassware means, When it is fixed to this glassware means using a fixing means provided in this cap, and a corresponding fixing means provided in this glassware, this cap is fixed to this glassware and it fastens, in order to prevent leakage from this container of a fluid, this cap, A container on which this fixing means acts mutually so that this seal may be fixed to this glassware means.

[Claim 15]The container according to claim 14 with which said cap has a fixing means of a screw thread which exists in an inner surface of this cap as 1 set, and a screw thread which exists around said edge of said glassware means corresponding to it.

[Claim 16]The container according to claim 14 which has a fixing means used as a fastener for said cap to fix to said glassware means.

[Claim 17]Said cap is a plastic snap type cap which equips this cap with one fixing means which is an edge intermittent at least, The container according to claim 14 which is heights which enclose intermittently at least the circumference of said glassware means by which a fixing means by the side of this glassware means to correspond exists in an end along an edge of a lengthwise direction of this glassware means.

[Claim 18]The container according to claim 17 which has the hole which was equal to said opening of said glassware for said plastic snap type cap to pick out said fluid from said container on a tip surface.

[Claim 19]The container according to claim 17 in which said plastic cap is hardening polymer.

[Claim 20]The container according to claim 17 which is hardening polymer chosen from a group which said plastic cap becomes from polycarbonate, thermoplastic polyester, polyacrylate, its mixture, and an eutectic mixture.

[Claim 21]The container according to claim 17 which contains a disk-like gasket for absorbing a shock between this snap type cap and this seal in this plastic snap type cap when said cap is put on said container and said opening of this container is covered with said seal.

[Claim 22]The container according to claim 1 with which derivation seal of said binder is carried out at said glassware means.

[Claim 23]The container according to claim 1 with which heat seal of said binder is carried out at said glassware means.

[Claim 24]The container according to claim 1 with which said glassware means has an opening at the end of both sides where it is cylindrical and this pillar counters.

[Claim 25]. Accommodate a fluid for a quality control in a calibration and/or a blood gas analyzer. . Are a hermetic container which can sterilize and have a diameter of a range from an effective size of population to a size of the minimum side of this container for receipts and payments of a fluid. Are a glassware means with at least one opening, and an edge is extended around this opening, and thickness of this edge, . In order to secure this opening from wall thickness of this container, it is a range to thickness slightly smaller than a radius of this container, a glassware means and b — they are inactive lining substances which have at least two surfaces, such as a metallic foil with which it is a seal of impermeableness [air] and the first surface is chosen from aluminum and copper, substantially.

The second surface is adhesive polymer chosen from a group which consists of heat active adhesive, a pressure sensitive adhesive, and derivation seal adhesives, and this second surface of this seal this opening in order to suppress an outflow of gas substantially to a wrap sake. A fixing means which is the cap which fully contacts surface area of this container, and which fixes a seal and c this seal to this glassware means, and was provided in this cap. It is fixed to this glassware means using a corresponding fixing means provided in this glassware, So that this seal may be fixed to this glassware means in order to prevent leakage of a fluid in this container when this cap fixes this seal and is fastened for this glassware means, This fixing means acts mutually and this cap is a plastic snap type cap of rigid polymer which can

be fabricated, May have a hole in a tip wall and it has one fixing means which is an edge intermittent at least in alignment with the circumference of a vertical plane inside this cap, When fixing means by the side of this glassware means to correspond are the heights intermittent at least in alignment with the circumference of this glassware means which exist along an edge of one of lengthwise directions of this glassware means, a gasket which has a size which agrees inside this cap, It is a cap and a fluid which contains a fluid and gas at d room temperature which are included between a tip of an inner surface of this cap, and this seal, When stored by this container, this fluid contains at least gas which dissolved in this at least one kind of fluid of a known amount, If this container is thoroughly filled so that headspace may be provided, it is not, but percent by volume to this headspace of this fluid is less than about 99 to about 1%, A container with which this opening of this glassware means has a diameter of a comparatively small value also in the range of a size of this opening of this glassware means when one sort of gas of a known amount which is dissolving into this fluid is oxygen and containing a fluid.

[Claim 26]The container according to claim 25 with which said corresponding fixing means is the downward outer side screw mountain provided in a circumference surface of said glassware, and said cap has a downward inside screw thread around a side wall.

[Claim 27]The container according to claim 25 which generally has a circular periphery and a diameter so that said seal may carry out the seal of said opening circumference of said glassware means and which is generally a flexible circular disk.

[Claim 28]The container according to claim 25 which a hole of said cap is a hole of a center section, and has an annular edge which has the inside peripheral ring which provided caudad a hollow part which maintains distance from a flat tip part for stopping under said edge where this cap leads to heights of said glassware.

[Claim 29]The container comprising according to claim 25:

Said plastic cap is a tip wall.

A circumference side attachment wall which has a downward screw thread inside.

[Claim 30]Said glassware means has cylindrical shape and has an opening of a diameter of a range up to about 1 to about 10 millimeters at the end, . This glassware means has a diameter of a range up to at least 3 to about 10 millimeters. Are the container according to claim 25, said seal of impermeableness substantially is impermeableness also at oxygen and carbon dioxide, and, in said fluid, oxygen tension even by 0 to 760 mm Hg. A container whose carbon dioxide partial pressure is a standard fluid [finishing / a pressure survey] which has the concentration of atmospheric gas beyond one sort or it, such as oxygen and/or carbon dioxide, even by 0 to 760 mm Hg.

[Claim 31]The container according to claim 25 percent by volume to said fluid of said headspace is [container] up to about 77 to about 23 percents by volume.

[Claim 32]The container according to claim 25 by which said headspace is filled with an inert gas atmosphere.

[Claim 33]The container according to claim 25 currently filled with a gas atmosphere chosen from a group which said headspace becomes from a mixture with inactive gas beyond oxygen, carbon dioxide, those mixtures and one sort, or it.

[Claim 34]The container according to claim 33 whose concentration of said carbon dioxide concentration of said oxygen is a range from below external concentration to more than external concentration, and is a range from below external concentration to more than external concentration.

[Claim 35]Said fluid is equilibrated by mixed gas containing carbon dioxide, oxygen, and inactive gas, The container according to claim 25 which is filled by the same gas as what was used for said headspace preparing this balanced liquid, and is chosen from a group which this gas becomes from oxygen, carbon dioxide, inactive gas, and its mixture.

[Claim 36]Said fluid Sodium chloride, potassium chloride, ammonium chloride, a lithium bromide, An alkaline metal and alkaline earth metal chlorides, such as potassium phosphate and sodium phosphate, A bromide and a phosphorylation thing; Water-soluble hydrogencarbonates, such as an alkaline metal and/or an alkaline-earth-metals hydrogencarbonate, And aerated water matter lithium, sodium bicarbonate, potassium bicarbonate, Hydrogencarbonate; and absorption of carbon dioxide to which cations, such as a hydrogencarbonate containing aerated water matter magnesium, ammonium acid carbonate, and aerated water matter dimethylammonium, originate in ammonia or amine, . Or buffer in order not to be influenced by addition of acid or a base but to maintain the pH of solution. The container according to claim 25 with which it is solution which dissolves and contains one sort or a salt beyond it chosen from other buffer salts

and a group, ** and others, and a salt of a quantity effective in order to obtain a suitable pressure so that said fluid may be equilibrated by at least one sort of gas exists.

[Claim 37]The container according to claim 25 currently filled with a gas atmosphere chosen from a group which said headspace becomes from nitrogen, carbon bisulfide, carbon monoxide, methane, other hydrocarbon gas, ozone, and its unreacted mixture.

[Claim 38]In order to accommodate a fluid for a quality control of a calibration and/or a blood gas analyzer, Glassware which is a manufacturing method of a sterilization hermetic container and has an opening of a range from an effective size of population to a size of the minimum side of a container for receipts and payments of a fluid, So that percent by volume to headspace of a fluid may become by less than about 99 to about 1%, A process with which a fluid is filled so that it may leave headspace, and it may not fill thoroughly, a process of purging b this headspace by one sort or gas beyond it, c) The first surface that is inactive substances which are impermeableness substantially and are separated from this opening to air in this opening of this container, such as a metallic foil, The second inner surface that is at least one sort of adhesive polymer with a seal which it has A wrap process, d) How to include a process of sealing a glassware means of two or more vials with this seal, and a process of checking at least one leakage of a container of which f sterilization was done, by a process, e heat, or the derivation sealing method which fixes this seal to this glassware by a physical fixing means.

[Claim 39]A way are a manufacturing method of the sterilization hermetic container according to claim 38 which includes preparing a fluid [finishing / a pressure survey] which contains a fluid and gas in a temperature requirement from below a room temperature to beyond a room temperature, and this fluid dissolves and contains gas of at least one sort of known amounts at least.

[Claim 40]It is a hermetic container in which sterilization for accommodating a solid, a fluid, or gas is possible, a). Have a diameter of a range from an effective size of population to a size of the minimum side of this container for receipts and payments of a fluid. Are a glassware means with at least one opening, and surround this opening, and an edge is extended, and thickness of this edge, . In order to secure this opening from wall thickness of this container, it is a range to thickness slightly smaller than a radius of this container, a glassware means and b — it is an impermeable seal substantially to air which has at least two surfaces, and the first surface is inactive lining substances, such as a metallic foil chosen from aluminum and copper.

The second surface is adhesive polymer chosen from a group which consists of heat active adhesive, a pressure sensitive adhesive, and derivation seal adhesives, and this second surface of this seal this opening in order to suppress an outflow of gas substantially to a wrap sake, . Have a hole in a seal and c tip wall which fully contact the surface of this container. It is the plastic snap type cap of fabricated rigid polymer, It is fixed to this glassware means by fixing means of this cap, and a fixing means to which this glassware corresponds, In order to prevent at least one fixing means's being an edge of the circumference intermittent at least, corresponding fixing means' being heights of the circumference intermittent at least, and contents of this container leaking, When this cap fixes this seal and is fastened to this glassware, this fixing means agrees at a tip of an inner surface of a cap and d this cap which act mutually, A container containing contents of this container chosen from a group which consists of a disk type gasket formed between this cap and this seal and e solid, a fluid, gas, and its mixture.

[Claim 41]Said plastic snap type cap Polycarbonate, thermoplastic polyester, . It is rigid polymer chosen from a group which consists of polyacrylate, its mixture, and an eutectic mixture. In order that it may be the container according to claim 40 and a hole of this cap may take out contents of this container, A container with which it is in an apical surface together with this opening of this glassware, this edge fixing means had a hollow part in the lower part, it has projected thoroughly from the circumference of an inside vertical plane of this cap, and a fixing means to which said heights correspond is provided in an edge along either of the perpendicular directions of this glassware.

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DETAILED DESCRIPTION

[Detailed Description of the Invention]

[0001]

[Industrial Application]Also in various contents, this invention was sealed substantially that the fluid for the calibration for blood gas analyzers (proofreading) or a quality control can be stored especially, or relates to the container in which airtight sterilization is possible substantially.

[0002]

[Description of the Prior Art]Many small containers are used in fields, such as a container the drugs vial for the injector medication in a medical field or a "disposable" vial, the blood serum vial of other molds, and for the standard fluids for body fluid analysis. One of the containers conventionally used in these fields has a glass ampul. For example, the standard fluid which has publicly known oxygen and a carbon dioxide partial pressure has been dramatically dedicated by the ampul to the use in the measuring instrument of many marketing. Some of these instruments measure the oxygen tension and/or carbon dioxide partial pressure in various physiological fluids. A standard fluid controls the quality by measuring the concentration of these gases in a physiological fluid. For example, although it includes that an blood gas analysis measures the partial pressure of these gases in an arterial blood sample, in order to extract blood from a test subject and to pour it into an analyzer in this case, it is conveyed to a laboratory.

[0003]In order to have to notch in order to take out a fluid, and to have to break it, the glass ampul is troublesome if a glass ampul is used in this field. A user can be injured when the notched edge of the glass ampul which broke when attaching and breaking a notch is touched, since such a procedure is required. In order to avoid the infectious illness, it is in the present age which must be stopped to the minimum about touching a blood sample, and such a procedure must improve. Although using a plastic instead of a glass ampul can be solved, a new problem is also born by it. If solution is dedicated to a plastic bottle, it will have been pointed out in the preservation over a long period of time that a solution will lose. When a plastic container is used, the inner gas ratio of the saved standard fluid [finishing / a pressure survey] may change temporally. The preservation solution exceeding 10% loses in the retention period of two years, and the partial pressure of gas exceeding 10% may lose. Such loss is not admitted by the medicine preparation of B.P. which has defined the percent change in the solution durability of an active principle to 10% or less, or U.S.P. The container without good sealing performance is not suitable for the standard fluid in an blood gas analysis, and/or calibration fluid.

[0004]These days, the standard fluid container which does not have air bubbles in a container and which is a flexible airtight container is proposed by US,4,116,336,B. This flexible container may be a lamination bag of aluminium foil which has a inner layer of the plastic in which the heat seal with high weldability with low gas permeation nature is possible. The aluminium foil of this container has sufficient thickness without the danger that a detailed hole will open. For example, the plastic in which heat seal of a polyacrylonitrile copolymer is possible can be sealed by welding a plastic layer. When the container is filled about this container, it is indicated by maintaining the total gas pressure in the fluid of less than 600 mmHg at 37 °C that air bubbles can be lost. If this patent is not looked out for continually to the existence of air bubbles or formation in the reference solution object sealed hermetically in the tight container, it is teaching that a big change of the data measured about the reference solution object, especially oxygen tension may take place.

[0005]It is industrially necessary to be easier to use than a glass ampul, and for neither a scratch crack nor a detailed hole to open easily unlike a flexible aluminium container, and to provide the tight container for drugs and/or a blood serum vial with long storage life of the reference solution object to save, and a standard fluid.

[0006]

[Summary of the Invention] One aspect of affairs of this invention is a hermetic container which is effective as the standard for quality controls, such as blood-gases measurement, or calibration fluid for the rheometry, and is obtained, which encloses the fluid which dissolves and contains at least one sort of gas in a fluid and which can be sterilized. This container has [as opposed to / at least / air] substantially the glassware means or vial which has an opening in an end, and an impermeable seal and the fluid which is a fluid which has at least one sort of solution gas of a known amount. As headspace exists in a container, the quantity of the fluid in a container is a small quantity rather than filling a container thoroughly. The percent by volume to the headspace of a fluid is about 99 to less than about 1% of range. There are an internal surface and an outside surface in a seal, an outside surface is the metal of not oxidizing on a real target like aluminum, and an internal surface is adhesive polymer. A seal is fixed to glassware so that the opening of a container may be covered. This immobilization can be performed by physical means, such as a chemical means and/or a cap.

[0007] It has an opening of the diameter of the range up to about 1 to about 10 millimeters at the end, this glassware means has an inside diameter up to at least 3 to about 50 millimeters, and said seal of impermeableness substantially of the glassware means of this invention is impermeableness also at oxygen and carbon dioxide.

And said fluid from 0 in the oxygen tension in the range to 0 to 760 mm Hg, and the range to 760 mm Hg with a carbon dioxide partial pressure. It is a container which is a standard fluid [finishing / a pressure survey] which has the concentration of the atmospheric gas beyond one sort or it, such as oxygen and/or carbon dioxide.

[0008] The container of this invention has cylindrical shape.

[0009] The container of this invention is a container whose percents by volume of said headspace to said fluid are about 77 to about 23 percents by volume.

[0010] In another aspect of affairs of this invention, the cap used is a specific cap which is a plastic snap type cap on the glassware which has an opening in an end and has a seal. This cap has a wrap skirt part for the edge of glassware. Inside the skirt part, the binding in which a binding corresponds to the apical surface of glassware is provided, respectively. It fixes, and these bindings get into gear so that glassware may be stopped, so that a snap type cap may not leak contents from a container. The apical surface of a cap has an opening on an axial center section or the outskirts of it, and the apical surface is connected with the skirt part exceeding the end of the level surface of glassware, or an apical surface. This opening is arranged with the opening of glassware so that contents can be picked out from a container.

[0011] The manufacturing method of a sterilization hermetic container for enclosing the fluid for the calibration in [in / further / another aspect of affairs] a blood gas analyzer of this invention and/or a quality control is provided. This method prepares the fluid [finishing / a pressure survey] containing a fluid and a gas. The thing fulfilled by a fluid to few grades rather than filling thoroughly the glassware which has at least one opening at the end. It includes fixing a seal to glassware by covering the opening of a container with an impermeable seal substantially to air, heat, or derivation seal, sterilizing a container, and checking at least one leakage among sterile containers.

[0012]

[Elements of the Invention] As shown in drawing 1, and 5 and 6, a fluid may exist in the vial 10. When it has a snap type cap as the vial 10 showed to 7 from drawing 4, this fluid 12 especially, Drugs dedicated from the former into a blood serum vial and a substance, or a standard fluid. Or they may be fluids, such as a mixture of a fluid containing diffused gas or a fluid which considers it as a contrast fluid for a standard, gas chromatography, or gas analysis as drugs, and is used, and gas, or all analytical reagents.

[0013] When at least one sort of gas which the fluid 12 dissolved in a fluid is contained, a kind of gas. Only oxygen is crossed to wide ranges, such as a mixture of carbon dioxide or oxygen, carbon dioxide, and gas of others, such as air, and a mixture of gas of various kinds which contain various quantity of air to gas contained in the air. Gas of other kinds is also independent or may exist in a form of a mixture. An unreacted mixture of nitrogen, carbon bisulfide, carbon monoxide, methane, other similar hydrocarbon gas, ozone, and these gas and atmospheric gas is contained in it.

[0014] Generally, a standard fluid as the fluid 12 is solution which has at least one sort of diffused gas. Generally this method and solution prepared Salt, NaCl, potassium chloride, A chloride of an alkaline metal and alkaline-earth metals like ammonium chloride, a lithium bromide, potassium phosphate, and sodium phosphate. An aqueous solvent which has one sort or fused salt beyond it, such as water-soluble hydrogencarbonates, such as a hydrogencarbonate of a bromide, a phosphorylation thing and an alkaline

metal, and/or alkaline-earth metals, and a hydrogencarbonate to which a cation originates in ammonia or amine, is contained. As an example of a hydrogencarbonate, aerated water matter lithium, sodium bicarbonate, potassium bicarbonate, aerated water matter magnesium, ammonium acid carbonate, aerated water matter dimethylammonium, etc. are mentioned. Since it is an most economical and desirable salt, it is preferred to use sodium bicarbonate. Such quantity is only quantity which is required in order to obtain a pressure almost corresponding to a pressure of a fluid to analyze. In this point, these water-soluble mineral salt acts so that solution may be buffered. Generally, if a buffer salt is added to solution, it will maintain pH, without receiving influence in addition of an absorptivity of carbon dioxide, acid, or a base.

[0015] Generally, gas in the fluid 12 may be manufactured by person skilled in the art by publicly known arbitrary methods. For example, although a standard fluid can be obtained from Instrumentation Laboratory under the name of IL237, with any pressure survey meter [like] of marketing. Or as reference. It has used. "Quality Control in Blood pH and Gas Analysis by Use of a Tonometered Bicarbonate Solution and Duplicate Blood . Are indicated in a report entitled Analysis in Clinical Chemistry" (Vol. 27, No. 10, 1981, 1761 ~ 1763 pages). It may be a fluid [finishing / a pressure survey] which can be manufactured also by publicly known arbitrary methods to a person skilled in the art like art shown by preparation of buffer solution [finishing / a pressure survey] or whole blood liquid. Diffused gas changes the quantity to many vials, and it may be prepared so that a series of vials containing gas of various concentration may be made. Such a series of vials can act as a standard of a calibration gas determination device. As for solution, it is most preferred to contain oxygen and carbon dioxide for being buffered and using as a quality control standard in a blood gas analyzer or carry BURANTO (standard substance for proofreading). Such a solution may be prepared according to US,3,681,255,B used as reference.

[0016] In this Description and attached Claims, it uses [term / "it equilibrates"] in a meaning recognized in the field concerned that gas and buffer solution contact mutually and are held until an equilibrium situation is acquired between gas which dissolved in the liquid phase, and gas which is not dissolving. It was equilibrated as the fluid 12, or an example of a standard fluid [finishing / a pressure survey] can be acquired by the ability to contact carbon dioxide containing gas which may contain a mixture of a buffered solution and inactive gas beyond carbon dioxide, one sort, or it. Inactive gas is a gas to which it does not react to buffer solution and pH is changed. It becomes impossible for this reason, to predict the last pH value. Inactive gas is a gas reacted to neither of the ingredients in a standard fluid. As an example of inactive gas, nitrogen, argon, and a similar gas of others which are usually seen in the air are mentioned. Rare gas, such as neon, argon, krypton, a xenon, and helium, is also contained in this. It is preferred to be with carbon dioxide and nitrogen or to use a mixture of carbon dioxide and nitrogen containing oxygen as balanced gas for an blood gas analysis. A thing whose remainder about 5% of gas in 1 fluid is carbon dioxide, and is oxygen as two examples, and 2 about 7 volume % are carbon dioxide, about 10 volume % is oxygen, and thing ** whose remainder is nitrogen is mentioned.

[0017] Gas of controlled quantity is contained, or in order to prevent change of a partial pressure value, and change of a pH value, a standard fluid equilibrated by gas is into a system, or is maintained in environment where diffusion of gas from a system or a steam is prevented. A device recognized in the field concerned can be used in order to maintain this standard fluid, but as that example, a pressure gauge (tonometer) of the above-mentioned marketing is mentioned.

[0018] The fluid 12 as a standard fluid may contain one sort or a compound beyond it, in order to promote the fusibility of specific gas in a buffered solution. Publicly known arbitrary compounds may be used for a person skilled in the art.

[0019] In drawing 1, the vial 10 is a glass vial which has the edge 18 which encloses and contains the opening 16. By a tip part, the edge 18 is substantially flat, and it is designed so that the opening 16 may be formed on the seal 20 in add-on of various molds of a wrap sake. Although the vial 10 can have arbitrary sizes publicly known to a person skilled in the art as containers, such as a blood serum vial, it is preferred that it is a cylindrical shape, it is more round, or can also form a bulb-shaped container. The vial 10 has the head field 14 which can take arbitrary forms for supporting the opening 16 of a container. A gently-sloping angle may be sufficient as a shoulder part connected with the head field 14 also at an angle near right-angled towards the opening 16. As for the vial 10, it is preferred to have only a shoulder part which can form a crater portion in the head field 14 between a shoulder part of the vial 10 and a lowermost end of the edge 18. Although the vial 10 may be manufactured with arbitrary standard glass compositions for preparing a container, what is known for the field concerned as I-beam borosilicate glass is mentioned as one of the suitable constituents. Generally, a minimum diameter of an opening beyond one or it of the vial 10 (16) is only a diameter which does not interfere with receipts and payments to the vial 10 of the fluid 12. A maximum diameter of an opening is only a diameter which can secure the edge 18 which fully has the

surface where a tip which encloses the opening 16 is level, as it touches by a periphery so that the edge 18 and the seal 20 may cover the opening 16. As for the opening 16, it is preferred that it is an opening of a center of the vial 10 which is extended in accordance with a major axis of the edge 18 and the head field 14, and continues inside a center opening of a vial containing the fluid 12. As for the vial 10, it is more preferred to have a size in following within the limits. A diameter of an opening is about 1 to about 10 mm, wall thickness about 0.5 to about 1.5 mm, and an inside diameter is about 3 to about 50 mm, and length is about 3 to about 200 mm. The vial 10 may have the second opening that is not similar to the above-mentioned opening, or similar at the end which counters the first cylindrical opening. The second opening has the seal 20 with which the first opening was shown.

[0020]The seal 20 of drawing 1 is a laminated structure of a monolayer of impermeableness [air], or a multiplex layer substantially. As a suitable monolayer material, a metallic foil which can be sealed with a possible polymeric material of heat treatment or RF (high frequency) processing for seal is included. A charge of a laminated material of a multiplex layer usually has an internal layer and a metallic foil layer of the outside of a polymer raw material. A typical laminated structure has two or a layer beyond it, and may have a print on a polymer layer for raising abrasion resistance outside further, or a metallic foil layer. Aluminum is mentioned as an example of a metallic foil. :1 nylon in which three suitable layer systems for a seal of this invention may have the following towards an inner layer from lateral surface, An inside polymer layer in which heat seal of polyester, polyethylene or polypropylene, 2 aluminium foil and 3 polyethylene, polypropylene, and polyvinylidene chloride, nylon, etc. is possible. Specifically Nylon of 17 g/m^2 , aluminum of 32 g/m^2 , Polypropylene of 45 g/m^2 or a suitable nylon foil-polypropylene laminated structure of an example is a Polly foil-poly lamination of three layer systems which has the inside and an outer layer of a central layer of aluminium foil, and polypropylene. The upper layer 22, i.e., a portion, is separated from the mouth 16, i.e., an opening, of the vial 10.

The lower layer 24, i.e., a portion, touches glass of the edge 18.

As for the seal 20, it is preferred that it is the aluminium foil which carried out the coat with a tunic in which transparent heat seal is possible and which was backed with paper. As for this tunic, it is preferred that it is a mixture of the amount ethylene-vinylacetate copolymer of Polymer Division available with a trade name of Sancap (161 Armor Street NE, Alliance, Ohio 44601) to "SANCAP". Gas permeability [as opposed to oxygen in such a material] is 0.

Transmissivity to a steam is 90% of relative humidity, and 0.005 per 24 hours - 0.059GS (gram) / OSI (100 square inches).

Such a material will serve as an impermeable seal to air substantially, if it fixes to the opening 16 of the vial 10 firmly. By Ox-tran 1000, water permeability of the above-mentioned value is Permatran-W6, and oxygen permeability is obtained, and these two devices, It is more nearly available than Mocon, Modern Controls, and Inc. (6820 Shingle Creek Parkway, Minneapolis, Minnesota 55430). 8 mils of thickness of the seal 20 are about 4.6 to about 7.8 mils preferably from about 4 as a whole.

about 4 mils of thickness of a heat seal tunic are about 1.5 to about 3 mils preferably from about 1 --- thickness of aluminium foil --- about 0.1 to about 2 mils --- and it is about 0.3 to about 1.65 mils more preferably.

[0021]Or the seal 20 has the adhesive substance 24 which is suitable thermoplastics for a hot melt deposit or extrusion lamination. As a suitable example for such thermoplastics, resin publicly known as what is called hot melt adhesives, such as polyethylene, ethylene / vinyl acetate copolymer (EVA), or EVA by which partial saponification was carried out, is mentioned. As polymer of a main chain part, for example, 15 to 45% of the weight of vinyl acetate. A graft copolymer which is a 20 to 60% saponification thing of the ethylene/vinyl acetate copolymer (EVA) which has polymer of acid in which an unsaturation was carboxylated can be used as polymer of a branching part into 0.1 to 10% of the weight of partial saponification EVA. The seal 20 may be a complex of the aluminum/polypropylene membrane which has resin in which heat seal of polyamide, polyolefine, saturated polyester, etc. is possible. When adhering to a glass surface, sealing resin and pasting up a seal on the vial 10 by heat seal, publicly known arbitrary derivation seal or a heat sealing method may be used for a person skilled in the art. A sealing method is based also on a fixing means for a certain grade maintaining the seal 20 in the state where it inserted in a flat face of the edge 18 exactly. The seal 20 covers the opening 16 thoroughly and can take suitable arbitrary forms to be exactly restored to a flat face of the edge 18. As for the seal 20, it is preferred that it is a disk type which has a diameter near a diameter of the edge 18.

[0022]Generally, in drawing 1, if the standard fluid 12 fills the vial 10 thoroughly, it is not, but it forms the

headspace 26. When the fluid 12 is a fluid drug which exists in the vial 10 which has a snap type cap, headspace is made to exist and inactive gas can also be packed on a fluid drug, but it is not necessarily required. Generally, the headspace 26 is filled with one sort or gas beyond it which is not similar to a vacuum, inactive gas, or gas that is dissolving in the fluid 12, or similar. As for the headspace 26, when applying to blood-gases measurement, it is preferred to fill with balanced gas which is dissolving in the fluid 12.

[0023]An example of a suitable method for putting the standard fluid 12 of an initial complement in the vial 10, purging the headspace 26 by gas of a required presentation, putting the seal 20 on a flat face of the edge 18, and fixing the seal 20 to the edge 18 firmly like drawing 1 is as follows. It holds putting a pressure on a field put to a high frequency electromagnetic wave in the vial 10 of drawing 1 which has the seal 20 which covers the opening 16. It is available in a suitable device as Giltron Inc. (Medfield, Massachusetts 02052) to Foil Sealer Induction Heat Sealer, and Model PM1. It heats selectively to a grade which dissolves a glue line which adjoins aluminium foil of the seal 20. A dissolved resin layer adheres to the level surface at a tip of the edge 18 which encloses the opening 16. If the conventional capping device is used in order to perform such an derivation seal process, high-speed processing called about 200 seals is possible in 1 minute. In order to make the seal 20 fix to the edge 18 more firmly, it is possible to use a chemicals coupling agent for a glass surface of the edge 18. As a suitable example of such a coupling agent, ORGANO titanate, such as organosilanes, such as vinyltriethoxysilane and gamma glycid oxy propyltrimethoxysilane, tetrapropyl titanate, or tetrabutyl titanate, is mentioned.

[0024]Oxygen gas is dissolving in the fluid 12, or oxygen gas is contained in the headspace 26, and when measurement or concentration of oxygen in the vial 10 is important, a diameter of the opening 16 is adjusted. With "regulation", in order to limit surface area of a layered product put to an ingredient of the headspace 26 and/or the fluid 12, I hear that a diameter of an opening is held down to minimum, and it is. All reactions of oxygen in the headspace 26 and/or the fluid 12, and metal of a layered product and/or adhesive polymer are limited by this.

[0025]Drawing 2 shows another shape of the head field 14 of the vial 10. The head field 14 can take any forms, if an opening from the vial 10 is securable. Drawing 2 has here an angle to a body area of the vial 10 shown with the numerals 30 from the head field 14 with the looser shoulder part 28 of the vial 10, although a thing of drawing 1 shows different shape. Such a vial is preferred when a snap type cap is used for fixing the seal 20 to the opening 16, as shown in drawing 4.

[0026]With the screw type cap 32 shown in drawing 3, the seal 20 can fix to the edge 18 exactly. In each figure, the same numerals show the same portion. Thus, after making it adhere exactly, in order to paste glass and to seal thermoplastic polymer, sufficient heat seal to dissolve thermoplastic polymer can be performed in a container. In drawing 3, metal, a plastic, or what kind of conventional substance may be sufficient as it, and if the cap 32 is appropriate, what kind of shape may be sufficient as it. It is most preferred to use hardening plastics, such as polyester Mr. polyethylene terephthalate or polycarbonate, those mixtures, or an eutectic mixture. The cap 32 has the apical surface 34 and the side 36 (shown by drawing 3 as lateral surface) which has a screw thread which goes caudad in an inside. An inside diameter of the cap 32 is more slightly [than an outer diameter of the surrounding edge 18 of the opening 16] large, and the cap 32 gets into the head field 14 exactly. The vial 10 has the head field 14 where an upper bed is connected with the opening 16. A fixing means corresponding to a screw thread of the head field 14 which is a fixing means in the cap 32 most at the outside is established. This fixing means is the outside screw thread 38 which makes the head field 14 of the vial 10 rotate the cap 32, and is united with a screw thread in the cap 32.

[0027]The seal 20 which has the upper layer 22 of a metallic foil of gas impermeableness, and the lower layer 24 for heat seal of thermoplastic adhesion polymer, The seal 20 is placed on the opening 16, it hangs over a flat face of the edge 18, and the cap 32 has come to fit into the seal 20 exactly so that it may have a diameter slightly smaller than an inside diameter of the cap 32 and the cap 32 can hold the seal 20. In order for the glass vial 10 to apply torque generally to such an extent that where does not break, sufficient torque to insert the seal 20 in the glass vial 10 exactly is also effective power, so that heat seal can be used from derivation seal. If this torque is not enough to insert the seal 20 in an edge of glass exactly so that the opening 16 may be covered as a vacuum or a fluid in gas in the headspace 26 or the headspace 26 does not leak from a vial, it will not become. Even if it has a hole of a diameter of whether it is slightly small or large so that it might agree in a diameter of the opening 16 of the vial 10 or may lead to the opening 16 via the seal 20, it is not necessary to have a screw type cap. By using an elastomeric gasket between the cap 32 and the seal 22, it is also possible to improve the importance of torque concerning the screw type cap 32. Although such a gasket is not shown in drawing 3, it is similar to what showed a cap of

drawing 5.

[0028]Drawing 4, and 5, 6 and 7 show a desirable embodiment of this invention using the glass vial 10 with a snap type plastic cap. Here, in giving details of Drawings, the same numerals are given to the same member. Generally, as for the glass vial 10, in length, 1 to 2 inches and a diameter have a size of 1/4 to 1/2 inch. As for the vial 10, it is preferred to have a shoulder part of a loose angle which was described in a portion of above-mentioned drawing 2 so that power given in a device on which a snap type cap is put can be borne. A cap shown in drawing 4 as the snap type cap 40 has got into the edge 18 of the vial 10 exactly.

[0029]Drawing 5 is a section notch figure of this. With the cap 40 put on the edge 18, it becomes the relation which fitted in exactly in this way. the seal 20 which has two layers, i.e., the upper layer 22 of aluminum and the lower layer 24 of thermoplastics, — the edge 18 top — and the opening 16 is covered and it is located. The elastomeric gasket 42 is between the topmost part of the snap type cap 40, and an aluminum layer of the seal 20. This gasket 42 has an outer diameter which is carried on the vial 10 in the snap type cap 40, without harming the seal 20. As for this outer diameter, it is preferred that it is the almost same size as an inside diameter of the cap 40. As for this gasket 42, it is preferred to have the hole 46 of a size corresponding to the hole 44 of the snap type cap 40. However, as long as the gasket 42 has a damping effect, cushion effect, or the impact-absorbing effect when the snap type cap 40 is inserted in the vial 10 so that the seal 20 may remain appearing on the glass vial 10, a diameter of the hole 46 can be changed. As for this gasket 42, it is preferred that about 7 per square centimeter — a pressure of 14 kg of abbreviation can be borne. A diameter of the hole 44 of the snap type cap 40 can also be changed. It must be a diameter which can extract the fluid 12 from the vial 10 at the minimum using a needle of a small gauge. It must be only a diameter which leaves the minimum apical surface 34 which carries the cap 40 on the vial 10, and an apical surface of the edge 18 may be made to seal exactly at the maximum. Seal carried out exactly is obtained by engaging the fixing means 48 of the cap 40 to a fixing means of the vial 10. A corresponding fixing means by the side of the vial 10 is the crater portion 50 which is just under the bottom of the edge 18. The fixing means 48 is the ring type projection on a medial surface of a skirt part of the cap 40. Although a continuous thing is preferred, each surface of the fixing means 48 and the crater portion 50 is also intermittent, and they are obtained. When intermittent, a height and the crater portion must agree mutually to a grade to which are sufficient size and the vial 10 is made to fix the cap 40 firmly. Any suitable fixing means, such as establishing a circular sulcus in a medial surface of a skirt part of the cap 40, and establishing an annular projection edge which gets into a slot of the cap 40 in the circumference surface of the edge 18 generally, can be used. One with the preferred snap type cap 40 which has the height 48 is because it is more economical than to manufacture a glass vial which has a height to manufacture a cap which has a height.

[0030]Drawing 6 shows a snap type cap of a plastic similar to a thing of drawing 5 which does not have the gasket 42. In another embodiment of this this invention, the same numerals as a thing of drawing 5 are used for the same parts. The hole 44 of the cap 40 is larger than what was shown in drawing 5. This shows that a size of the hole 44 of the cap 40 has pliability. Such modification can be made, even if it uses a gasket and does not use.

[0031]Drawing 7 is a section notch figure of the snap type cap 40 which has the apical surface 32, the hole 44, and the annular ring 52. A mirror image portion of this snap type cap also exists in a portion which is not shown in drawing 7 since it is a notch figure. In order to insert in the vial 10 exactly, distance from an inner surface of the apical surface 32 shown by the inner surface 50 to the upper surface of the annular ring 52, It is large slightly from height of the edge 18 to the bottom of the annular edge 18 shown as 56 which is the Mogami end of the crater portion 50 from the upper surface of the edge 18 shown in drawing 5 and 6 as 54.

[0032]As shown in drawing 1, and 5 and 6, volume of the headspace 26 which exists in the vial 10, and an ingredient of this headspace are decided by some factors. A retention period of a request of a fluid as this factor, the necessity for sterilization, and its kind, . [whether it is used as a standard fluid for contrast of a kind of gas in a standard fluid, gas concentration, and a fluid, and] It is mentioned whether being used as calibration fluid for a blood-gases measuring instrument or a fluid is drugs and whether headspace is an inert atmosphere to a fluid.

[0033]When a retention period used as a standard fluid may be a short thing of four or less days, volume very small within the vial 10 may be sufficient as the headspace 26. In this case, about 10 volume [of internal volume of the vial 10] % may be sufficient as the headspace 26, and the standard fluid 12 may be more than 90 volume %. In order to obtain a long retention period beyond one year or it from about six months, volume % of the headspace 26 must be increased. This increase is to about 90 volume %, and

volume % of the standard fluid 12 is about 10% of the internal volume of the vial 10. In order to obtain a retention period of about six months, volume % of the headspace 26 is about 70 to 80, and it is preferred to make the standard fluid 12 into about 20 to 30 volume %.

[0034]An ingredient of gas in the standard fluid 12 also affects quantity of the headspace 26 at condition that the headspace 26 may be slight when only carbon dioxide exists. Oxygen must be independent, or when it exists in the standard fluid 12 as a mixture with other gas, and when [in order to obtain a desired retention period,] maintaining fixed oxygen pressure within the vial 10, volume % of the headspace 26 must be dramatically large. When volume % of the standard fluid 12 is too large, or in being too small conversely, oxygen pressure decreases time later on.

[0035]Generally, an ingredient of the headspace 26 may change by an example of application from a vacuum to inactive gas, or a fluid and common gas. A vacuum may be made by arbitrary methods accepted in the field concerned. Although an ingredient may be inactive gas like nitrogen, this purges a vial, after adding the fluid 12. An ingredient of the headspace 26 may also be gas which dissolved in the standard fluid 12, or its mixture. For example, when oxygen can be made into gas in the headspace 26 when oxygen is dissolving in the standard fluid 12, and mixed gas of oxygen and carbon dioxide is dissolving in a standard fluid, for example, an ingredient of the headspace 26 may be a mixture of oxygen and carbon dioxide.

[0036]Concentration of gas in the headspace 26 may change also by concentration of the fluid 12, and processing of various vials 10. For example, when sterilizing the vial 10 by gamma irradiation, initial oxygen concentration may change about a certain kind of fluid composition. The gas composition thing in the headspace 26 can buffer all reduction of oxygen in the vial 10 with a method which consumes oxygen of a kind of sterilization, i.e., a gamma sterilization method, and others. The amount of oxygen compensated may exist in the headspace 26, in order to cope with this effect. About application to carry BURANTO, carry BURANTO has the oxygen pressure from below outdoor air pressure to more than outdoor air pressure, and usually has the carbon dioxide pressure from below outdoor air pressure to more than outdoor air pressure.

[0037]It may lead to other factors which have on volume of headspace according to a kind of application of a fluid in a vial. For example, when it is a standard fluid for a fluid to apply to contrast or carry BURANTO, a fluid of different gas concentration is enclosed with a separate vial, and a series of vials which have the gas concentration from which each differed can be formed. It is also possible to add arbitrary antiseptics publicly known to a person skilled in the art to the standard fluid 12. moreover — when applying as contrast, once it opens the vial 10 — a part for a divisor — between — it is desirable to maintain fixed gas pressure through vial duration of service. For this reason, headspace 26 must be made small and the opening 16 of the vial 10 must also be made small. In application to carry BURANTO to which a vial and/or carry BURANTO may contact a patient, a vial and its contents must sterilize. Sterilization can be performed by heat pasteurization and/or a gamma sterilization method. When gamma sterilization of the vial which has enclosed a fluid which has oxygen gas is carried out, there is a tendency for oxygen pressure of a fluid to change. When using this kind of sterilizing method, volume [of headspace] % and its presentation must be changed according to a case.

[0038]By an application method, a relation between sizes of volume % of the headspace 26, volume [of the fluid 12] %, and the opening 16 of the vial 10 may be materialized. A flat apical surface of the annular edge 18 becomes small as the opening 16 of the vial 10 becomes large, but. In order to perform seal according to a kind of sterilization suitable processing of the vial 10, for example, derivation seal, or heat seal, and if needed, sufficient flat face to contact the seal 20 must exist.

[0039]When sealing a vial, even if it could keep carbon dioxide pressure and pH constant, a problem that oxygen pressure decreased temporally arose. By using headspace containing gas of suitable concentration, fixed oxygen pressure can be provided during a desired period. A diameter of an opening of a vial is made small and fixed oxygen pressure has been maintained over at least eight months by performing these processings.

[0040]The partial pressure of gas in headspace can be beforehand set up using an experiential method by publicly known physical chemistry principle and/or the gas soluble effect. Concentration of mixed gas of marketing which carried out the bubble is contained in this until it will be in predetermined headspace, temperature, and an equilibrium situation. A sufficient number of samples are tested continuously and a statistical profile of a partial pressure is obtained.

[0041]When full of a vial before seal, a vial is gas, for example, inactive gas, and can be purged once [at least]. As for purge gas, when applying to blood gases, it is preferred to have the same presentation as what was used for manufacturing a standard fluid or the carry BURANTO fluid 12. As for enclosing the fluid 12 with the vial 10, although arbitrary methods publicly known to a person skilled in the art may be used, it

is preferred to enclose from a saved area which prepares quantity of a request of gas which dissolved into a fluid. It leaves fixed space as the headspace 26, and the fluid 12 is enclosed with a vial. Before the headspace 26 installs the seal 20 in the vial 10, it goes into the vial opening 16 and is usually purged by desired gas using a needle of a thin gauge which gives a blanket of purge gas to the headspace 26. In order to purge the headspace 26 and to prevent an outflow of gas and a fluid, the vial 10 is quickly sealed by inserting derivation seal or the seal 20 in the vial 10 for the vial 10 exactly only with the seal 20.

[0042]A sealing method [in / intrinsically / the flat tip end part 54] with the seal 20 of the vial 10 shown in drawing 5 and 6 is based on existence of a cap, and a kind of thermoplastic adhesion polymer 24. Derivation seal must be used in order to prevent an outflow of gas from the headspace 26 and the fluid 12, or an inflow of gas to them, when there is no cap. When using a screw type cap or a snap type cap, derivation seal can also be used, but it is more desirable to use heat seal. When using heat seal and a cap is a screw type cap, torque with an appropriate screw type cap must be given. Since humidity or a fluid may exist in the surface 54 of the edge 18, generally, in seal, it is moist environment and it is necessary to conquer difficulty of pasting up the thermoplastic adhesion polymer 24 on glass.

[0043]In using a screw type or a snap type cap, the seal 20 is put on a cap and it installs the cap in a vial containing the fluid 12 and the headspace 26. In this case, it is not necessary to use a coupling agent for a glass surface of the edge 18. A publicly known conventional screw type or a snap type capping device can be used for a person skilled in the art. In a suitable capping device to use for a screw type cap, it is available from Cozzoli Machine Company (Plainfield, New Jersey). Another example is indicated to US,4,030,271,B and this is indicating a device designed in order to rotate to a bottle or a vial held at a standard rack or a holding fixture and to attach or remove a screw type cap to it. As for this device, it is preferred to put a cap on each vial continuously at least. A changed screw type capping device similar to what can be obtained from Cozzoli Machine Company as an example of a device on which a snap type cap is put is mentioned. An alteration of this device is transposing to arbitrary devices publicly known to a person skilled in the art for applying sufficient power to press a cap of a tip part of a vial until a fastener gets a member for a screw type cap of this device into gear so that a cap may be fixed to a vial. For example, a pneumatic pressure ramming device can be used.

[0044]A cap is attached by a suitable method that the seal 20 is exactly inserted in the surface of a glass vial at the edge 18, a vial is processed so that it may seal thoroughly, but it is preferred to process two or more vials by a batch process. Two or more vials can be heated till softening temperature of thermoplastic polymer which can become the adhesion raw material 24, or resin at arbitrary suitable furnaces publicly known to a person skilled in the art. When it is not the temperature which rose and temperature falls to a room temperature at least, it is preferred to maintain sufficient time for polymer to flow suitably and this temperature so that the seal 20 may paste the glass vial 10. When the seal 20 contains SANCAP ethylene and a vinyl acetate copolymer, it is most preferred to install two or more vials in a furnace, and to heat to temperature of 50 to 80 **. It is preferred that about 8 hours generally maintains this temperature from about 1. The more it heats for a long time within the limits of this, the more it becomes enough also for sterilization of a vial by being not only enough to cause a flow of thermoplastic polymer but pasteurization. When other sterilizing methods are used, time is shortened within the limits of this, and a vial can be sealed.

[0045]Two or more vials can be heat-sealed or derivation sealed about a vial which capped. A pressure given by heat seal temperature and cap may change with the kinds of heat sealing-performance resin used as the charge 24 of a binder. However, generally, if it carries out at a temperature higher than softening temperature or the melting point of heat sealing-performance resin, sufficient result will be obtained, and if heat sealing-performance resin of a portion which is distant from a seal field does not flow out superfluously, it can be said that a pressure is also enough. A seal pressure according to a screw type cap about heat seal of polypropylene heat sealing-performance resin for heat seal at temperature of the range of 180 to 280 ** is 2 per square centimeter to 5 kg (kg/square centimeter). For heat seal about polyamide heat sealing-performance resin like Nylon 12 at temperature of about 200 to 300 **, a pressure is 2 per square centimeter to 7 kg. For heat seal in a 220 to 320 ** temperature requirement about polytetramethylene terephthalate, a seal pressure is 2 per square centimeter to 7 kg. Time required for heat seal changes with the thickness of a heat sealing-performance resin layer.

[0046]Generally, heat seal is performed for 5 seconds from sufficient time, for example, 0.1, to perform the dissolution and combination of seal resin. Operation which consists of one, two, or a process beyond it can perform heat seal operation. In the case of two or more processes, same or different temperature and pressure conditions can be adopted at those processes. In this way, by arbitrary means for forming a seal field which has good sealing performance for a formed seal field if needed, a pressure is given and it cools.

For example, immediately after heat seal operation, resin presses a heat seal field which is still in softening or a solution state with two cooled press bars, and resin is solidified. However, in order to cool adhesion polymer and to solidify, publicly known arbitrary operations can be used for a person skilled in the art.

[0047]When the fluid 12, the headspace 26, and the vial 10 need to be sterilized, one or more sealed vials can be sterilized with a gamma sterilization method or pasteurization, as an example of pasteurization art in which it can use for a sterile container of this invention, heating one or a container beyond it at about 70 °C for 8 hours is mentioned. Gamma irradiation sterilization can be performed to a person skilled in the art using publicly known arbitrary gamma sterilization equipment. About pasteurization, the cooling rate must attain all the heating processes given to a vial within a suitable period.

[0048]It fills so that a manufacturing method of a seal vial of this invention may not be thoroughly full of a vial beyond one or it. It includes covering an opening with an impermeable seal to air substantially, fixing a seal to a vial, sealing two or more vials, and testing leakage of a vial. A vial is filled so that it may leave in a vial headspace purged by one or gas beyond it. For example, when using a vial as a carry BURANTO container, a fluid [finishing / a pressure survey] which contains a fluid and gas at a room temperature can be prepared. When applying in this way, this fluid at least has the gas of at least one sort of known amounts which dissolved into a fluid. Glassware is filled with this fluid by receipts and payments of a fluid through an opening of a range from an effective size of population to a size of the minimum side of a container. Headspace may be the range of less than about 1 volume % from about 99 volume % to a fluid. An opening of a container containing a fluid and gas has an internal surface and an outside surface, and is substantially covered with air with an impermeable seal. That outside surface is inactive lining substances, such as a metallic foil, an internal surface is adhesive polymer, and this seal is a wrap about an opening of glassware. A seal is fixed to glassware by physical fixing means, such as a cap. Two or more vials seal glassware with a seal by heat seal or derivation seal. Arbitrary furnaces publicly known to a person skilled in the art which can store two or more desirable vials and can be heated to a desired temperature can perform heat seal.

[0049]At least one of two methods can perform a quality control of the sealing performance of a vial. One method is observing leakage of two or more vials by detecting existence of moisture under a specific vial between change of fluid volume in a vial or heat seal. Another method is turning so that it may put under decompression of two or more sealed vials and a seal's may contact a fluid in a vial. It is preferred to carry out a vial for reverse so that a fluid in a vial may contact a seal of a vial thoroughly. Although the decompression does not necessarily need to be a vacuum, in order to cause leakage of a seal so that reduction of volume of a fluid in a vial, moisture from a vial, or existence of exudation may become clear, it must be the low pressure near a vacuum.

[0050]Drawing 8 is the graph which took time (Mon.) on a vertical axis along a partial pressure (pO_2) (millimeter Hg) of oxygen by mercury, and a horizontal axis in two sorts of vials. A vial of both kinds was a snap type cap vial which is shown in 7 from drawing 4, and was stated to following working example 1. Although a vial of one kind was called the following "A type", it was sealed so that there might be no headspace, and did not provide an opening in a cap. A diameter of an opening of A type vial is 4.5 mm. Area of an opening was 63.5 square millimeters.

pO_2 in this condition is shown by the curve A. Although a vial of the second kind was called the following "B type", it was sealed so that it might have the headspace of 54 volume %, and had a small opening on a cap. A diameter of an opening of B type vial is 1.75 mm.

Area of an opening was 9.6 square millimeters.

pO_2 in this condition is shown by the curve B. Surface area of foil put to contents of a vial by difference of area of an opening changed with A type and B types. In drawing 8, over six months, although pO_2 of the curve B was comparatively constant, it has fallen to 0 by 180 to about five months, and a half with the curve A. Thus, it is based on a vial of this invention which has the structure of maintaining headspace and its headspace and has an opening of a small diameter sealed with aluminium foil of an adhesive material that oxygen gas pressure can be kept constant over six months. This fixed oxygen gas pressure continues six months or more till 12 months at present.

[0051]In drawing 9, reduction of [in six months of the two same sorts as what was tested by drawing 8 of two or more vials] of a carbon dioxide partial pressure (pCO_2) was tested. In addition to two sorts of vials, pCO_2 of two different levels was tested. Drawing 9 shows that pCO_2 of two levels is not influenced by a difference of a diameter of an opening of headspace and/or a vial.

[0052]

[Example]In working example 1, it manufactured by purging a vial by the gas used for making a fluid [finishing / a pressure survey / vial / like drawing 1], and the fluid [finishing / the pressure survey] was added so that the vial might not be filled thoroughly. The vial was again purged by the same gas, the aluminium foil side was carried out outside and Sancap aluminum two-layer foil was installed on the vial. The tip of a vial in which foil was formed, it pushes against the single-phase external bar of Foil Sealer Induction Heat Sealer Model No. B1 (Giltron Inc., Medfield, Massachusetts) by the output wattage 775, It held sufficient period for derivation seal of the foil seal to be carried out at a vial, and there.

[0053]In working example 2, the plastic snap type cap which has the gasket and seal which were shown in 7 from drawing 4 was installed on the vial 10 so that it might be inserted into the gasket 22 between the undersurface on the surface 32 of a cap, and the apical surface 18 of the vial 10. The aluminum surface of the Sancap two-layer substance seal was distant from the glass surface. The snap type cap was installed in the vial by the fixture to the screw type capping device which changed the device of Cozzoli Machine Company. This device was changed by transposing the screw type cap corresponding point of a device to pneumatic pressure rum. In order to apply sufficient power to push the cap which exists at the tip of a vial until a cap fits into a vial firmly (a snap is carried out), the edge drooped vertically at the tip of a snap type cap. When a cap was fastened to a vial, the gasket was pressurized by the pressure between 7 kg per square centimeter bet on the two-layer aluminium foil 20 which has covered the opening of the vial, and 14 kg. Since a gasket supplies the pressure for fixing the seal 20 to the edge of a vial before a seal process or between them, derivation seal and heat seal can also be used.

[0054]This invention provides the seal vial for dedicating a fluid. This fluid may be a standard fluid for carry BURANTO which dissolves and contains gas and drugs, or gas analysis. This vial is a glassware means to have at least one opening. The size of an opening is in within the limits from a size exactly good for taking a fluid in and out to the size of the minimum side of a container. The edge is extended around the opening. A vial is not thoroughly filled with a fluid so that it may leave headspace to an inside. This headspace exists in a vial at a rate of 1 to 99 percents by volume to a fluid. A vial is sealed with an impermeable double lamination seal to the air which consists of adhesive polymer in contact with a vial, and an outside surface of metal. Since a seal is fixed to a vial before heat-sealing or derivation sealing a vial, fixing means, such as a cap or a chemicals coupling agent, are used. When a cap is a snap type cap, a gasket may be used between a cap and a seal. A vial may sterilize, and may be processed as two or more vials between heat seal and derivation seal, and can perform arbitrary sterilization according to the application purpose.

[Translation done.]

* NOTICES *

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2.*** shows the word which can not be translated.

3.In the drawings, any words are not translated.

DESCRIPTION OF DRAWINGS

[Brief Description of the Drawings]

[Drawing 1]In order to cover an opening, it is an expansion sectional side elevation of the container of this invention to which the glass vial was made to stick two seals or the seal of the two-layer structure by a chemical means.

[Drawing 2]It is a notch sectional side elevation of the tip part in the state where the container which has the screw type cap or blockade part which fixes a seal to a glass vial was sealed.

[Drawing 3]It is an expansion exploded view of the tip part of the container which has the screw type cap except the notch of drawing 2.

[Drawing 4]It is an expansion side view of the container which has the snap type cap which fixes a seal to a glass vial.

[Drawing 5]It is a sectional side elevation of the tip part of a vial which has a gasket and has the snap type cap which fixes a seal to a glass vial.

[Drawing 6]It is a sectional side elevation of the tip part of a vial which does not have a gasket but has the snap type cap which fixes a seal to a glass vial.

[Drawing 7]It is a strabism sectional view of drawing 4 and the snap type cap tip part of the container of 5 and 6.

[Drawing 8]It is the graph on two separate conditions which took the oxygen tension by a mercurial column (millimeter Hg) along the vertical axis, and took time (Mon.) along the horizontal axis.

[Drawing 9]It is the graph on two separate conditions which took the carbon dioxide partial pressure by a mercurial column (millimeter Hg) along the vertical axis, and took time (Mon.) along the horizontal axis.

[Description of Notations]

10 Vial

12 Fluid

14 Head field

16 Opening

18 Edge

20 Seal

22 Upper layer

24 Lower layer

26 Headspace

[Translation done.]

* NOTICES *

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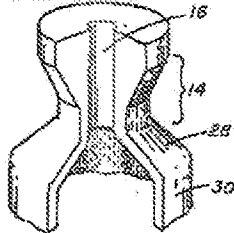
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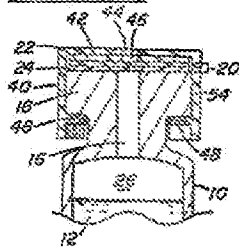
3.In the drawings, any words are not translated.

DRAWINGS

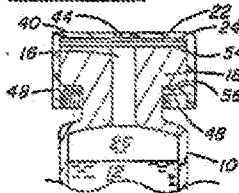
[Drawing 2]



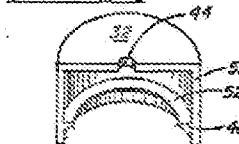
[Drawing 5]



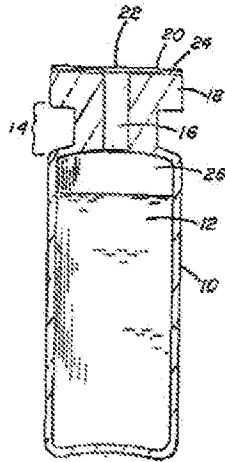
[Drawing 6]



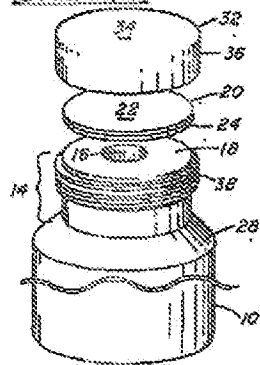
[Drawing 7]



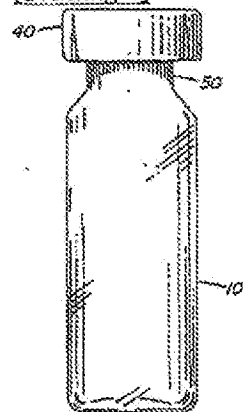
[Drawing 1]



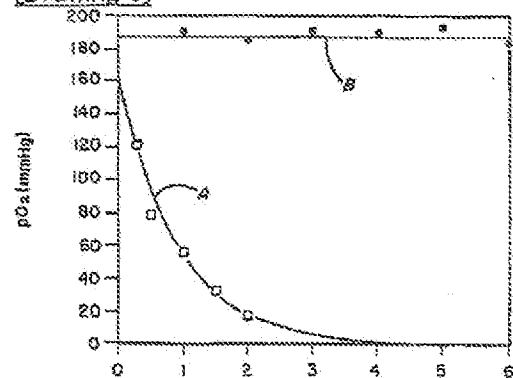
[Drawing 3]



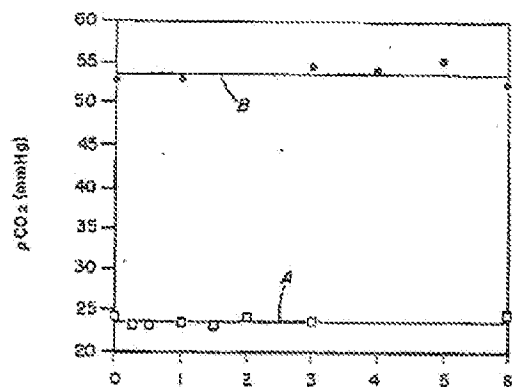
[Drawing 4]



[Drawing 8]



[Drawing 9]



[Translation done.]